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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,501	02/09/2004	Leena Peltonen	084500-000100US	2308

20350 7590 10/11/2006

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EXAMINER	
CHO, DAN SUNG C	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,501	PELTONEN ET AL.	
	Examiner	Art Unit	
	Dan-Sung C. Cho	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *41-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 41-75 are pending.

Election/Restrictions

1) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 41-52, 55-56, 75 drawn to DNA, vector, host cell and composition and a kit, classified in class 536, subclass 24.1.

II. Claims 51-52, drawn to a transgenic animal, classified in class 800, subclass 8.

III. Claims 51-52, drawn to a transgenic plant, classified in class 800, subclass 295.

IV. Claims 53 and 54, drawn to SNP-specific antibodies, classified in class 530, subclass 388.21.

V. Claims 53 and 54, drawn to SNP-specific aptamers, classified in class 536, subclass 23.1.

VI. Claims 53 and 54, drawn to SNP-specific phages, classified in class 435, subclass 6.

VII. Claims 56-67, 72-75, drawn to a method of diagnosis of a disease traits association study, classified in class 435, subclass 440.

VIII. Claims 55, drawn to a method of pharmaceutical treatment, classified in class 514, subclass 44.

IX. Claims 68-71, drawn to a method of testing for hypolactasia with an antibody, classified in class 435, subclass 440.

1. Inventions I to VI are drawn to products; VII to IX, to methods. Inventions VII and VIII are drawn to compositions intended for use in diagnosis or treatment. Composition inventions 55 and 56 are divided into two groups with the first group, limited to composition, grouped with product group I (nucleic acids). When composition inventions, 55 and 56, are grouped with Group I, no weight is given for the diagnostic and pharmaceutical treatment aspects. Conversely, when inventions 55 and 56 are grouped with VII and VIII, the inventions are considered as treatment or diagnostic inventions and their functional limitations will be examined, not the compositions per se. For example, when invention 56 is grouped with VII, the nucleic acid disclosed is treated as treatment invention as a diagnostic agent.

2. Groups I, II, and III, IV, V and VI, are distinct and unrelated from each other because the structure, function and utilities of a nucleic acid (I) are different from those of a transgenic animal (II), a transgenic plant (III), antibody (IV), an aptamer (V), or a phage (VI). Nucleic acid is composed of nucleotides; protein, polypeptides. For example, a nucleic acid is made up of nucleotides while a protein, amino acids. A search for the inventions of each group will not be coextensive with searches for other invention group. Although antibodies in Group IV may bind to same DNA as aptamer and phage, antibodies have unique characteristic structures that are distinct and unrelated from aptamer and phage. Phage requires of phage library while antibody and aptamer do not. Aptamer encompasses in vitro selection that require materially distinct

steps antibody and phage do not require. A search for the antibody inventions of Group IV will not be coextensive with searches for page or aptamer invention groups V and VI. Transgenic animal of II are distinct and unrelated from transgenic plant of III because of differences in structure, function and utilities. Transgenic animals and plants require either transgenic animal or plant that other product inventions do not encompass.

3. Method inventions in Groups VI, VIII and IX are distinct and unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions encompass chemically distinct compounds such as antibody (IX) and nucleic acid (VII and VIII). Although groups VII and VIII both encompass nucleic acid, the inventions are distinct because VII is drawn to a diagnostic method while VIII encompasses pharmaceutical aspects. For example VII requires use of agents such as restriction enzymes to determine DNA sequence while VIII does not. A search for the inventions of a polymorphism detection of Group VII will not be coextensive with searches for inventions of a pharmaceutical composition method of VIII.

4. Inventions I and VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the DNA in

Group I can be used to determine gene expression profiling and in situ hybridization patterns not related to either diagnosis or pharmaceutical methods of VII and VIII.

5. Inventions IV to VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case antibody, aptamer or phages in Group IV to VI can be used to determine tissue specific distribution of DNA sequences not related to either diagnosis or pharmaceutical methods of VII and VIII.

Restriction Requirement Applicable to All Groups:

2) Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications. A restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

3) The claims I, VII and VIII contain three pairs of individual, independent and distinct nucleotide sequences in alternative form, namely wildtype and mutant at position (-13910), at (-22018, Claims, 54 and 55) and at (-22013, Claim 42 (d)). Accordingly, these claims are subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (November 19, 1996).

4) Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are

presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

5) Applicant is required to select one of the individual sequences for examination. The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

6) For Group I where the invention (Claim 50) is drawn to a combination of oligonucleotides, namely one or more oligonucleotides, a restriction is also applied. As provided in MPEP 803.04, "Applicants will be required to select one combination for examination." The selected combination will be searched and examined. A combination may be as few as a single oligonucleotide or as many oligonucleotides as the combination of all the recited oligonucleotides. Applicant is required to specifically indicate the single combination desired. All combinations containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed. Rejoinder will be permitted for claims requiring any allowable sequence(s). Any claims which have been restricted and nonselected and which are limited to the allowable sequence(s) will be rejoined and examined.

7) Additional restriction for Group IV, V and VI where the claims drawn to 3 distinct DNA-specific antibodies or aptamers or phages are disclosed, namely antibodies or aptamers or phages that specifically recognize DNA sequences T-G, C-A and C-G at positions (–13910) and (–22018). As provided in MPEP 803.04, Applicants will be

required to select one antibodies or aptamers or phages. Applicant is required to specifically indicate the single antibodies or aptamers or phages desired.

8) Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

9) Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dan-Sung C. Cho whose telephone number is 571-272-9933. The examiner can normally be reached on Mon - Fri, 7-4 EST.

11) If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12)Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dan-Sung C. Cho
Examiner
AU1634
September 29, 2006

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER